

REMARKS

Claims 1-49 were previously pending in this application. By this amendment, Applicant is canceling claims 1-6, 8-24, 28-37 and 42-48 without prejudice or disclaimer. Claims 7, 25-27, 38-40 and 49 have been amended. As a result claims 7, 25-27, 38-41 and 49 are pending for examination with claims 7, 38 and 49 being independent claims. No new matter has been added.

Rejections Under 35 U.S.C. §112 2nd Paragraph

The Examiner has rejected claims 7, 25-27, 38-41 and 49 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner has rejected the use of “/” as not being clear as to whether it denotes “and,” “or,” or “and/or.” Applicants have amended these claims to read “cell wall or plasma membrane to overcome this rejection. Support for this may be found within the specification on page 11, lines 29-31.

The Examiner rejected claims 25, 26, 38, 39 and 49 as lacking a comparative basis. Applicants have amended these claims to add a frame of reference to overcome this rejection.

The Examiner has rejected claim 27 as being indefinite. Applicants have amended this claim to delete the term “such as” to overcome this rejection.

The Examiner has rejected claim 40 as having no antecedent basis for the term “UCP inhibitor.” Applicants have amended claim 40 to depend from claim 39 to overcome this rejection.

Claim 49 lines 3-4 were rejected because it was unclear if there was a relationship between preventing an increase in oxygen free radicals and preventing infection in a plant. Applicants have deleted the phrase relating to oxygen free radicals in order to clarify the claim and because the phrase was not necessary for a complete claim. Also, as discussed below, there was a typographical error in this phrase. Amendment to claim 49 should be sufficient to remove each of these problems.

Rejections Under 35 U.S.C. §112 1st Paragraph

Written Description:

The Examiner has rejected claims 26-27 and 39-41 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement (Office Action page 2). The remainder of the rejection (Office Action page 2-4) refers to a lack of written description. Applicants have addressed the rejection as a lack of written description since this forms the basis of the substantive portion of the rejection.

The Examiner has indicated that the pending claims lack an adequate written description because applicant has not described an adequate number of species of UCP inhibitors. The Examiner has referred applicant to MPEP § 2163. MPEP § 2163 includes the following teachings: In reference to originally filed claims it is taught that “There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed *Wertheim*, 541 F.2d at 262, 191 USPQ at 96” (MPEP § 2163, II A.). The claims in question are original claims. There is literal support for them in the claims as filed as well as the summary of the invention.

According to the Office Action, “based upon the disclosure of SEQ ID NO: 1, 3, 5, and 7-12; nucleotides, nucleotide analogs, tocopherols, and non-omega-3, -6 fatty acids known in the art there is insufficient relevant identifying characteristics to allow one skilled in the art to completely determine the structure of a broad genus of UCP inhibitors, that inhibit UCP expression or activity, absent further guidance.” Applicants respectfully disagree.

“What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.” (MPEP § 2163, II A.3(a), paragraph 7).

The claimed invention is based on the discovery that UCP is present in specific areas of a plant, including the cell wall, cell membrane and chloroplasts. Prior to the invention it was already known that UCP was present in mitochondria. UCP and its role in regulating metabolism within mitochondria have been studied for many years. Many UCP binding peptides, such as antibodies were well known prior to the invention. It was also known that compounds such as specific types of fatty acids and nucleotides could be used to regulate UCP function. Applicant has not discovered a new class of compounds. The compounds were known in the art. Applicant has recognized that the known compounds can be used to target a molecule in a specific cellular location to regulate metabolic processes of the cell.

The MPEP provides examples that are relevant to the instant issue. Under the section related to description of a representative number of species it is taught “there are instances where one species adequately supports a genus. See e.g., *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326-27 (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to “adheringly applying” because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a “physiologically active steroid” and DMSO because “use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.” (MPEP § 2163, II A.3(a)ii, paragraph 2).

Applicant is using known compounds to perform a known function based on an important discovery relating to the presence of a protein (UCP) in specific cellular locations. Prior to the instant invention, to Applicants knowledge, the presence of such proteins in these locations was not known.

Unlike the above-described MPEP examples, applicants in this instance have not provided only a single example of a species to support a genus. Rather, Applicants have provided many examples of species and provided significant amount of support throughout the specification relating to the species. The Examiner has stated that the “Applicant does not describe UCP binding peptides, UCP antibodies, UCP dominant-negative nucleic acids or UCP encoding nucleic acid sequence other than SEQ ID NO: 1, 3, 5, and 7-12.” Applicants disagree with this characterization.

Applicants have provided a detailed description of UCP inhibitors throughout the specification, in particular they are described as “compounds which decrease the activity of UCP” (see for example page 23, beginning at line 3). UCP binding peptides are described in the specification at least on page 24, beginning at line 7. UCP antibodies are described in the specification at least on page 25, beginning at line 7. Applicants have also provided a detailed description of commercially available antibodies. Applicants describe the use of UCP dominant-negative cell wall or plasma membrane UCP polypeptides at least on page 32, beginning at the

first paragraph. UCP nucleic acids are described at least on page 13, beginning at line 16. UCP inhibitors are well known to those of skill in the art and Applicants have provided sufficient guidance to describe their use in methods to regulate UCP expression or reduce UCP expression in specific locations of a plant, i.e. cell wall, cell membrane or chloroplasts.

“An objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.’” (MPEP § 2163.02, first paragraph). In this instance, the specification provides an adequate description that allows one of skill in the art to recognize that the inventors have invented what is claimed.

Enablement:

The Examiner has rejected claims 7, 25-27, 38-41 and 49 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. According to the Examiner, “Applicant does not teach any methods of regulating fuel metabolism in a plant, or a method of decreasing UCP expression using any inhibitors of any kind or not, or a method of preventing infection in a plant, or a method for making a nutritionally enhanced plant by reducing UCP expression.” The Examiner also states that “Applicant has provided no guidance as to how UCP expression should be regulated, and how such regulation is correlated with regulating fuel metabolism in a plant; and there is no guidance for using any one of the broadly claimed UCP inhibitors.” Applicants respectfully disagree.

The application provides details of methods for regulating the expression of UCP in the cell wall or plasma membrane and hence regulating fuel metabolism (see for example page 10, beginning at line 4). Applicants provide details of increasing UCP expression which increases membrane potential and alters the cells ability to process energy and to grow more efficiently (see page 10, lines 5-10). A decrease in cell wall or plasma membrane potential by the inhibition of cell wall or plasma membrane UCP activity (page 10, lines 19-21) allows the cell to use alternative non-photosynthetic fuel sources as described on page 9, beginning at line 17.

The invention relates to the discovery that UCP is present in non-mitochondrial membranes. In view of this discovery it is now possible for one of skill in the art, following the guidance set forth in the specification to regulate cellular metabolism using the UCP inhibitors.

Applicant has demonstrated with working examples that UCP is present in cellular membranes other than the mitochondrial membrane. Further applicant has taught that if this non-mitochondrial UCP is manipulated using compounds that are known to manipulate UCP expression/function, that different metabolic states can be achieved in the plant cell. For instance by contacting a cell membrane UCP with a known UCP inhibitor it is possible to shift the plant to the use of alternative energy sources, causing the plant to accumulate fat, which can be harvested and also increasing oxygen free radicals which has been demonstrated to be useful in protecting a plant against infection.

The Examiner has pointed out a discrepancy in claim 49 with the specification. The Examiner correctly pointed out that on page 42, lines 6-16 the specification teaches that increased UCP expression levels were directly correlated with decreases in reactive peroxide oxygen species thereby suggesting that UCP functions to prevent increased levels of oxygen free radicals. This finding is found in other places of the specification, such as page 10 lines 19-31. A typographical error appeared in claim 49. The phrase "to prevent an increase in oxygen free radical" should correctly read "to promote an increase in oxygen free radicals". The proper reading is sufficiently supported in the specification. The amendment to claim 49 to delete the phrase should be sufficient to correct the problem.

The claimed methods would not require undue experimentation in view of the teachings found within the specification. Applicant has taught which membranes have UCP and how to regulate UCP in order to achieve the desired effect. UCP inhibitors are described throughout the specification but are also compounds known to those of skill in the art. If antisense is being used, one of skill in the art may need to identify which UCP is present in the membrane to be targeted prior to selecting the antisense sequence. This, however, does not constitute undue experimentation. The family of UCP proteins is limited in size and the nucleic acid sequences are known. In fact applicant has included a number of the known sequences in the sequence listing. To identify the UCP present in the membrane a simple hybridization reaction could be performed to identify the UCP. This is not undue experimentation.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 7, 25-27, 38-39, 41 and 49 under 35 U.S.C. §102(b) as being anticipated by Kowaltowski et al. The Examiner states that Kowaltowski et al. teach that

the activity of UCP was decreased in potato mitochondria upon the addition of ATP, and teaches the method steps of regulation of UCP expression and decreasing the expression or activity of UCP in a plant cell wall, a plant plasma membrane or a plant chloroplast by contact with a nucleotide inhibitor.

The claimed invention is based at least in part on the discovery that UCP is present in cellular membranes other than the mitochondrial membrane, i.e. cell wall membrane, and that the presence or absence of UCP in different membranes has important implications for the regulation of plant cell metabolism. Prior to the invention it was known that plant mitochondria contained UCP. The pending claims recite methods for regulating UCP expression in plant cell walls, membranes or chloroplasts but do not recite methods for regulating UCP expression in plant mitochondria.

Kowaltowski et al. describe a method for regulating mitochondrial UCP in a plant by contacting isolated mitochondria with ATP. Mitochondria were isolated from rat liver and potato tuber, incubated with BSA and ATP, phenylvaleric acid, linoleic acid, succinate, anti-mycin A, myxothiazol, and/or FCCP, and mitochondrial H_2O_2 generation or mitochondrial transmembrane electrical potential were measured. Kowaltowski et al. does not describe the presence of UCP in membranes other than mitochondria and does not regulate expression of UCP in membranes other than mitochondria. Therefore Kowaltowski et al. does not anticipate the instant claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 7, 25-27, 38-41 and 49 under 35 U.S.C. §103(a) as being unpatentable over Kowaltowski et al. According to the Examiner, Kowaltowski et al. teaches that antisense as an inhibitor of UCP activity would have been an obvious design choice because antisense inhibition is well known in the art.

For the reasons discussed above, Kowaltowski et al. does not render the pending claims obvious. Kowaltowski et al. does not contain any suggestion that UCP is present in membranes other than mitochondrial membranes. Thus the claimed invention would not have been obvious from the teachings of Kowaltowski et al.

Accordingly, withdrawal of this rejection is respectfully requested.

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CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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